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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/972,887	10/10/2001	Yoshinao Nagashima	214089US0CONT	4455

22850 7590 07/28/2003
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[REDACTED] EXAMINER

TRAVERS, RUSSELL S

[REDACTED] ART UNIT

[REDACTED] PAPER NUMBER

1617

DATE MAILED: 07/28/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/972,887	Applicant(s) Nagashima et al
Examiner R.S. Travers J.D., Ph.D.	Art Unit 1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Jul 7, 2003

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-20 is/are pending in the application.

4a) Of the above, claim(s) 15-20 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-14 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4

4) Interview Summary (PTO-413) Paper No(s). _____

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____

Art Unit:

The election filed June 7, 2003 1996 has been received and entered into the file.

Claims 1-20 are presented for examination.

Applicant's election with traverse of Group I, claims 1-14 in Paper No. 7 is acknowledged. The traversal is on the ground(s) that sesquiterpene alcohols are the special technical feature linking the disclosed inventions. This is not found persuasive because Group III lacks any special technical feature adapting the claimed apparatus for specific use with any compound. Although Applicants aver special technological features linking groups I and III, these assertions are without factual basis. As presented, claim 20 would read on any heating device contaminated by a speck of that natural product from which cedrol is conventionally extracted. Examiner additionally notes claim 3 recites numerous compounds not falling under the sesquiterpene alcohol penumbra.

The requirement is still deemed proper and is therefore made FINAL.

Claims 15-20 reading on non-elected subject matter are withdrawn from consideration.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit:

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, and thereby failing to provide an enabling disclosure.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence or absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art
- 7) the predictability of the art, and
- 8) the breadth of the claims.

Applicant fails to set forth the criteria that defines any composition which "has an odor below a detectable threshold". Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue

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experimentation. In the instant case, only a limited number of compositions which fail to possess "an odor below a detectable threshold" examples are set forth, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define the class of compounds required. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all compositions possessing "an odor below a detectable threshold" , necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

Claims 1-14 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 1-14 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-14 are rendered indefinite by the term "regulating" and thereby failing to clearly set forth the metes and bounds of the patent protection desired. Criteria defining the manner in which biochemical processes need be altered by medicaments in-vivo to "regulate" the autonomic nervous system are not set forth in the specification, thereby failing to provide information defining the instant inventions metes and bounds.

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Applicant's term fails to clearly define the subject matter encompassed by the instant claims, thus is properly rejected under 35 USC 112, second paragraph.

Claim 3 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is rendered indefinite by the phrase "sesquiterpene alcohol" and thereby failing to clearly set forth the metes and bounds of the patent protection desired.

Numerous examples of "sesquiterpene alcohol(s)" suitable for practicing the claimed invention fail to possess the requisite sesquiterpene structure. Absent specific exemplification, the skilled artisan could not establish the identity of compounds that would reside under the sesquiterpene alcohol penumbra herein envisioned.

Applicant's phrase fails to clearly define the subject matter encompassed by the instant claims, thus is properly rejected under 35 USC 112, second paragraph.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

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Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-14 are rejected under 35 U.S.C. § 103 as being unpatentable over Swada et al., and Binet et al.

Swada et al and Binet et al teach the claimed compounds as old and well known in combination with various pharmaceutical carriers and excipients in dosage forms. These medicaments are taught as useful for reducing stress and facilitating sleep, viewed by the skilled artisan as indistinguishable from those benefits herein claimed.

Claims 1-14, and the primary references, differ as to:

- 1) the recitation of effects provided to the autonomic nervous system,
- 2) the boiling point for the claimed compound,
- 3) the odor of the envisioned compositions, and
- 4) administration routes of the compounds.

The instant claims are directed to effecting a biochemical pathway with an old and well known compound. Arguments that Applicant's claims are not directed to the old and well known ultimate utility for this compound are not probative. It is well settled patent law that mode of action elucidation fails to impart patentable moment to

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otherwise old and obvious subject matter. Applicant's attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by things in the prior art, does not cause a claim drawn to those things to distinguish over the prior art.". Additionally, where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter, may in fact be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on. In the instant invention, the claims are directed to the ultimate utility set forth in the prior art, albeit distanced by various biochemical intermediates. The ultimate stress reduction, or somnolence providing utility for the claimed compounds is old and well known, rendering the claimed subject matter obvious to the skilled artisan. It would follow therefore that the instant claims are properly rejected under 35 USC 103.

It is generally considered that a compound and its physical properties are inseparable. Thus, possessing a compound; the skilled artisan would expect such compounds to be indistinguishable from other identical compounds. Examiner cited prior art teaches the compounds herein envisioned, for the therapeutic use herein envisioned, thus, this skilled artisan would expect the physical properties, such as the boiling point for such compounds to be identical, absent information to the contrary.

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Compositions which possess "an odor below a detectable threshold" are not specifically recited by the Examiner cited prior art. Teachings of therapeutic benefits herein envisioned are set forth in the Examiner cited prior art. The skilled artisan would expect those dosage levels providing the therapeutic benefits illustrated in the prior art to differ, from those functional dosage levels herein recited, not at all.

Claims 7 and 9-14 specifically require various conventional pharmaceutical compositions delivered by conventional routes of administration. Binet et al employed the claimed compound in an oral form, not specifically reciting another formulation. The skilled artisan would have seen all conventional compositions, and the administration of these compositions by all conventional means as residing in the skilled artisan purview.

No claims are allowed.

Any inquiry concerning this communication should be directed to Russell Travers at telephone number (703) 308-4603.



**Russell Travers J.D., Ph.D.
Primary Examiner
Art Unit 1617**